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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,440	FRADET ET AL.	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-65 and 67-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-65 67-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 1/30/09 in response to the Office Action of 9/30/08 are acknowledged and have been entered.

Claims 41-65 and 67-69 are pending.

Claim 65 has been amended by Applicant.

Claims 41-65 and 67-69 are currently under examination.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 41-50, 57, 58, 61, 63, 65, 67, and 68 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bussemakers et al (US 7,008,765 B1; filed 4/9/98) in view of Clements et al (The Journal of Urology, 4/99, 161: 1337-1343) and Goessl et al (Cancer Research, November 2000, 60: 5941-5945) for the reasons stated in the Office Action of 9/30/08 and for the reasons set-forth below.

The claims are drawn to methods for determining a predisposition for developing prostate cancer or a presence of prostate cancer in a patient comprising detecting PCA3 mRNA and a prostate-specific polynucleotide in urine samples from said patient comprising at least one prostate cell or nucleic acid thereof and not comprising semen.

Bussemakers et al teaches a sequence corresponding to PCA3, SEQ ID NO:6, that is 99.5% homologous to instant SEQ ID NO:9 and shares 99.6% local similarity to the first 2036 amino acids of instant SEQ ID NO:9 (see sequence comparisons). SEQ ID NO:6 is 100% identical to instant SEQ ID NO:10 (see sequence comparisons). SEQ ID NO:6 is 89.1% homologous to instant SEQ ID NO:13 and shares 99.6% local similarity to the first 3582 polynucleotides of instant SEQ ID NO:13 (see sequence comparisons). Due to the high degree of homology between SEQ ID NO:6 and instant SEQ ID Nod 9, 10, and 13, one of skill in the art would recognize that complements of SEQ ID NO:6 would hybridize to instant SEQ ID NOs 9, 10, and 13. Bussemakers et al further teaches a method for determining a predisposition for or the presence of prostate cancer in a patient comprising (a) performing an RT-PCR RNA amplification assay on a prostate biopsy sample comprising at least one prostate cell of said patient, or nucleic acid thereof, using a first primer pair specific to SEQ ID NO:6, (b) performing

a second RT-PCR RNA amplification assay on said sample using a second primer pair specific to PSA, (c) detecting in said sample an amount of PCA3 and PSA mRNA; and (d) wherein an increased level of PCA3 mRNA, as compared to the level of PCA3 mRNA in a sample from a normal subject, indicates that said patient will develop prostate cancer or that said patient has prostate cancer; and (e) wherein an absence of PCA3 mRNA or a lower level of PCA3 mRNA, as compared to the level of PCA3 mRNA in a sample from a normal subject, indicates that said patient will not develop prostate cancer and that said patient does not prostate cancer, when PSA mRNA is detected (Example 2, in particular). Further, PSA would hybridize to kallikrein 2. Bussemakers further teaches a method wherein said amplification assay is TMA (column 37, in particular). Bussemakers further teaches a method wherein said amplification of PCA3 and said PSA mRNA is performed simultaneously (column 36, in particular). Bussemakers further teaches a method wherein said detection is performed by chemiluminescence (paragraph bridging columns 15-16, in particular). By teaching PSA mRNA is detected in both benign and malignant prostate samples and that the level of PSA mRNA is not a reliable indicator of prostate cancer disease state, Bussemakers teaches a method wherein detection of PSA would validate a negative result for PCA3 detection in that the detection of PSA mRNA is indicative of the presence of prostate cells in a sample that did not display elevated PCA3 levels (Example 2, in particular). Bussemakers further teaches a method wherein said detection of PCA3 is carried out using chemiluminescent labels in a homogenous detection method (see paragraph bridging pages 15-16 and Example 2, in particular).

Bussemakers further teaches a method wherein said amplification of PCA3 and said second prostate specific nucleic acid is performed simultaneously in one container (see column 36, in particular).

Bussemakers does not specifically teach methods using a urine sample, a urine sample not containing semen, or a urine sample obtained after a digital rectal examination. However, these deficiencies are made up in the teachings of Clements et al and Goessl et al.

Clements et al teaches a method of using RT-PCR to detect PSA mRNA as a selective marker of prostate cells in urine from normal and prostate cancer patients (see abstract, in particular). Clements et al further teaches methods using urine samples from patients that have had digital rectal exams (left column of page 1338, in particular). Clements et al further teaches that PSA mRNA expression is intended to be used as a marker for prostate cells when screening patients for mRNA markers that are upregulated in prostate cancer cells of patients with prostate cancer (see paragraph flanking pages 1340-1341, in particular).

Goessl et al teaches a method of diagnosing prostate cancer using urine samples following a prostate massage in order to obtain urine samples with prostate cells to be analyzed for markers of prostate cancer (page 5941, in particular). Goessl et al further teaches that prostate massage is used to obtain urine samples comprising prostate cells in methods of diagnosing prostate cancer in older patients because ejaculates are not always easily obtained from older patients (left column of page 5944, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to diagnose prostate cancer in older patients using urine not containing semen from patients that have had a digital rectal examination, wherein the urine is collected as the first voided urine following a digital rectal examination and prostate massage as the sample of the method taught by Bussemakers et al because Goessl et al teaches that prostate massage is used to obtain urine samples comprising prostate cells in older patients (left column of page 5944), obtaining urine not containing semen collected following a digital rectal examination and prostate massage is less unpleasant and invasive than collecting a prostate biopsy, and combining two methods of detecting prostate cancer (marker detection and digital rectal examinations) would increase likelihood of detecting prostate cancer as compared to performing either method alone. In addition to reasons obvious from the teachings of Bussemakers et al, one of skill would have been further motivated to use PSA mRNA as a marker for prostate cells when screening for PCA3 mRNA in urine not containing semen that was collected following a digital rectal examination and prostate massage because Clemens et al demonstrates PSA mRNA expression as a marker for prostate cells when screening patients for mRNA markers that are upregulated in patients with prostate cancer (see paragraph flanking pages 1340-1341, in particular) and Bussemakers et al teaches PCA3 demonstrates 20-fold overexpression in prostate cancer cells as compared to PCA3 expression levels in prostate cells from patients without prostate cancer (column 37 of Bussemakers et al, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success using urine

not containing semen from patients that have had a digital rectal examination and prostate massage, collected following a digital rectal examination and prostate massage as the sample of the method taught by Bussemakers et al because Goessl et al teaches a method of detecting polynucleotides of prostate cells in urine not containing semen collected following a prostate massage (page 5941, in particular) and Clemens et al teaches methods comprising performing digital rectal examinations. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

In the Reply of 1/30/09, Applicant argues that none of the cited references indicate that PCA3 mRNA can be found in urine. Applicant further argues that both the ejaculate and the urethral washings of Clements contain semen and the instant claims recite methods using urine not containing semen. Applicant further argues that Clements is silent on detection of a prostate cancer specific marker such as PCA3 mRNA. Applicant further argues that Goessl is silent on performing an RNA amplification assay, but rather teaches a method involving a DNA assay. Applicant further states that PCA3 mRNA can be unstable and degraded easily. Applicant further argues that the results of Goessl teach away from using a urine-based test for determination of prostate cancer because Goessl teaches only 36% of prostate cancer patients tested positive in urine following a prostate massage, while 94% of prostate tumor samples and 50% of ejaculate tested positive.

The amendments to the claims and the arguments found in the Reply of 1/30/09 have been carefully considered, but are not deemed persuasive. In regards to the

argument that none of the cited references indicate that PCA3 mRNA can be found in urine, one of skill in the art would expect to detect PCA3 mRNA in urine of prostate cancer patients because Bussemakers teaches PCA3 mRNA is elevated in prostate cancer cells (Example 2, in particular) and Clements and Goessl teach that prostate cancer cells are found in urine (see left column of page 1338 of Clements and left column of page 5944 of Goessl, in particular). Therefore, one of skill in the art would expect to detect elevated levels of PCA3 mRNA in samples, such as urine, containing prostate cancer cells.

In regards to the argument that both the ejaculate and the urethral washings of Clements contain semen and the instant claims recite methods using urine not containing semen, the urine after the prostate massage on older patients of Goessl does not contain semen. The specification acknowledges that "urine" is obtained after a digital rectal examination "or other means which increase the content of prostate cells in urine" (see paragraph 0073, in particular). Further, original claim 24 recites that a digital rectal exam increases the number of prostate cells in a urine sample. Clearly, this increase in number comes from the prostate being massaged during the digital rectal exam.

In regards to the argument that Clements is silent on detection of a prostate cancer specific marker such as PCA3 mRNA, Bussemakers teaches PCA3 mRNA as a prostate cancer specific marker (see Example 2, in particular).

In regards to the argument that Goessl is silent on performing an RNA amplification assay, Bussemakers teaches an RNA amplification assay (see Example 2, in particular).

In regards to the statement that PCA3 mRNA can be unstable and degraded easily, methods involving RNA amplification are routine in the art (see Example 2, in particular) and there are commonly used techniques to stabilize and prevent degradation of mRNA.

In regards to the argument that the results of Goessl teach away from using a urine-based test for determination of prostate cancer because Goessl teaches only 36% of prostate cancer patients tested positive in urine following a prostate massage, while 94% of prostate tumor samples and 50% of ejaculate tested positive, Goessl et al teaches that prostate massage is used to obtain urine samples comprising prostate cells in methods of diagnosing prostate cancer in older patients because ejaculates are not always easily obtained from older patients (left column of page 5944, in particular). Further, obtaining urine not containing semen collected following a digital rectal examination and prostate massage is less unpleasant and invasive than collecting a prostate biopsy.

Claims 41-50, 57, 58, 61-65, 67, and 68 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bussemakers et al (US 7,008,765 B1; filed 4/9/98) in view of Clements et al (The Journal of Urology, 4/99, 161: 1337-1343) and Goessl et al (Cancer Research, November 2000, 60: 5941-5945) as applied to claims 41-50, 57, 58,

61, 63, 65, 67, and 68 above, and further in view of Cheung et al (Journal of Clinical Microbiology, 10/94, 2593-2597) for the reasons stated in the Office Action of 9/30/08 and for the reasons set-forth below.

Teaching of claims 41-50, 57, 58, 61, 63, 65, 67, and 68 by the combined teachings of Bussemakers, Clements, and Goessl is discussed above. The combined teachings of Bussemakers, Clements, and Goessl do not specifically teach method of extracting RNA using a silica-based method. However, these deficiencies are made up in the teachings of Cheung et al.

Cheung et al teaches a method of extracting RNA from a sample using a silica-based method (pages 2593-2594, in particular). Cheung et al further teaches that the silica-based method is at least as sensitive and in certain circumstances more sensitive than traditional phenol-chloroform extraction (page 2593, in particular). Cheung et al further teaches that this improved sensitivity may be due to more efficient recovery by silica particles (page 2593, in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use silica particles as taught by Cheung et al in the methods of detecting a predisposition for and the presence of prostate caner by detecting RNA as taught by the combined teachings of Bussemakers, Clements, and Goessl. Further, one would have been motivated to do so because silica-based methods of RNA purification are at least as sensitive and in certain circumstances more sensitive than traditional phenol-chloroform extraction. Further, one of skill in the art would have a reasonable expectation of success in performing the combined methods

because silica-based methods of RNA purification are well known and conventional in the art.

In the Reply of 1/30/09, Applicant argues that Cheung does not cure alleged deficiencies of Bussemakers, Clements and Goessl. Applicant further states that Cheung teaches a method of detecting viral RNA in serum and does not teach a method of detecting PCA3 mRNA in urine.

The amendments to the claims and the arguments found in the Reply of 1/30/09 have been carefully considered, but are not deemed persuasive. The alleged deficiencies of Bussemakers, Clements and Goessl have been addressed above. Further, it is acknowledged that Cheung teaches a method of detecting viral RNA in serum and does not teach a method of detecting PCA3 mRNA in urine.

Claims 41-50, 57- 61, 63, 65, 67-69 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bussemakers et al (US 7,008,765 B1; filed 4/9/98) in view of Clements et al (The Journal of Urology, 4/99, 161: 1337-1343) and Goessl et al (Cancer Research, November 2000, 60: 5941-5945) as applied to claims 41-50, 57, 58, 61, 63, 65, 67, and 68 above, and further in view of Baret (EP 0 256 932 A2; 2/24/88) for the reasons stated in the Office Action of 9/30/08 and for the reasons set-forth below.

Teaching of claims 41-50, 57, 58, 61, 63, 65, 67, and 68 by the combined teachings of Bussemakers, Clements, and Goessl is discussed above. The combined teachings of Bussemakers, Clements, and Goessl do not specifically teach method using acridinium ester as a chemiluminescent label or wherein detection of PCA3 is

carried-out using acridinium ester. However, these deficiencies are made up in the teachings of Baret et al.

Baret teaches methods of chemiluminescent detection using acridinium ester compounds (page 4, in particular). Further, Baret teaches methods of chemiluminescent detection using acridinium ester compounds are particularly useful for nucleotide probe analysis because they provide very stable signals that are measurable for long periods of time (page 3, in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use acridinium ester compounds as taught by Baret with chemiluminescent detection methods as taught by the combined teachings of Bussemakers, Clements, and Goessl. Further, one would have been motivated to do so because Baret teaches methods of chemiluminescent detection using acridinium ester compounds are particularly useful for nucleotide probe analysis because they provide very stable signals that are measurable for long periods of time (page 3, in particular). Further, one of skill in the art would have a reasonable expectation of success in performing the claimed method since chemiluminescent detection using acridinium ester compounds is well known and conventional in the art.

In the Reply of 1/30/09, Applicant argues that Baret doe not cure alleged deficiencies of Bussemakers, Clements and Goessl.

The amendments to the claims and the arguments found in the Reply of 1/30/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that Baret doe not cure alleged deficiencies of Bussemakers, Clements and

Goessl, the alleged deficiencies of Bussemakers, Clements and Goessl have been addressed above.

Claims 41-51, 54, 57, 58, 61, 63, 65, 67, and 68 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bussemakers et al (US 7,008,765 B1; filed 4/9/98) in view of Clements et al (The Journal of Urology, 4/99, 161: 1337-1343) and Goessl et al (Cancer Research, November 2000, 60: 5941-5945) as applied to claims 41-50, 57, 58, 61, 63, 65, 67, and 68 above, and further in view of Buck et al (1999, Biotechniques, 27(3):528-536) for the reasons stated in the Office Action of 9/30/08 and for the reasons set-forth below.

Teaching of claims 41-50, 57, 58, 61, 63, 65, 67, and 68 by the combined teachings of Bussemakers, Clements, and Goessl is discussed above. The combined teachings of Bussemakers, Clements, and Goessl do not specifically teach a method comprising detecting PCA3 using a primer pair comprising SEQ ID NOs: 3 and 4 or a method comprising detecting PSA using a primer pair comprising SEQ ID NOs: 1 and 2. However, these deficiencies are made up in the teachings of Buck et al.

Buck et al teaches a study wherein 69 different primer sequences were submitted by 39 different laboratories and 95 control primers distributed at 3 base pair intervals across a 300 base pair oligonucleotide test sequence were analyzed (pages 528-529, in particular). It was determined that all the submitted primers functioned very well and almost all the "control" primers functioned very well (page 533). Only one the "control" primers functioned poorly; however, the poorly performing control primer

performed adequately under optimized conditions (page 533). Thus, under optimal sequencing conditions with highly pure template and primer, many of the commonly applied primer design parameters are dispensable (see page 528, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to perform the method taught by the combined teachings of Bussemakers, Clements, and Goessl by using a primer pair comprising SEQ ID NOs: 3 and 4 to detect PCA3 and a primer pair comprising SEQ ID NOs: 1 and 2 to detect PSA because Buck et al teaches that, due to the new generation of sequencing reagents (page 528, in particular), any sequences throughout a known oligonucleotide would be obvious choices to design a primer. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for performing the method taught by the combined teachings of Bussemakers, Clements, and Goessl by using a primer pair comprising SEQ ID NOs: 3 and 4 to detect PCA3 and a primer pair comprising SEQ ID NOs: 1 and 2 to detect PSA because Bussemakers et al teaches a method of using primers to detect PSA and PCA3 (Example 2, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

In the Reply of 1/30/09, Applicant argues that Buck does not cure alleged deficiencies of Bussemakers, Clements and Goessl. Applicant further argues that one of skill in the art would not have had a reasonable expectation of success using a primer pair comprising SEQ ID NO:3 and SEQ ID NO:4 to detect PCA3 and a primer pair

comprising SEQ ID NO:1 and 2 to detect PSA because Buck et al teaches that "under optimal sequencing conditions with highly pure template and primer, many of the commonly applied primer design parameters are dispensable" and the instant specification teaches that one embodiment of the claimed invention uses crude, unpurified or semi-purified samples which would not comprise "highly purified" template.

The amendments to the claims and the arguments found in the Reply of 1/30/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that Buck does not cure alleged deficiencies of Bussemakers, Clements and Goessl, the alleged deficiencies of Bussemakers, Clements and Goessl have been addressed above.

In regards to the argument that one of skill in the art would not have had a reasonable expectation of success using the recited primer pairs to detect PCA3 and PSA because Buck et al teaches that "under optimal sequencing conditions with highly pure template and primer, many of the commonly applied primer design parameters are dispensable" and the instant specification teaches that one embodiment of the claimed invention uses crude, unpurified or semi-purified samples which would not comprise "highly purified" template, Applicant is arguing limitations not recited in the claims. The instant method does not require an RNA amplification reaction to be performed in samples of any particular degree of purity.

Claims 41-50, 52, 53, 55-58, 61, 63, 65, 67, and 68 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bussemakers et al (US 7,008,765 B1; filed

4/9/98) in view of Clements et al (The Journal of Urology, 4/99, 161: 1337-1343) and Goessl et al (Cancer Research, November 2000, 60: 5941-5945) as applied to claims 41-50, 57, 58, 61, 63, 65, 67, and 68 above, and further in view of Schlegel et al (US 2002/0168638 A1; filed 1/24/01) for the reasons stated in the Office Action of 9/30/08 and for the reasons set-forth below.

Teaching of claims 41-50, 57, 58, 61, 63, 65, 67, and 68 by the combined teachings of Bussemakers, Clements, and Goessl is discussed above. The combined teachings of Bussemakers, Clements, and Goessl do not specifically teach a method comprising using molecular beacons, such as those that comprise SEQ ID NO:5 or SEQ ID NO:6, to detect PCA3 and PSA. However, these deficiencies are made up in the teachings of Schlegel et al.

Schlegel et al teaches methods of detecting prostate cancer comprising detecting PCA3 polynucleotides and PSA (paragraph 161, in particular). Schlegel et al further teaches methods of detecting markers of prostate cancer comprising using molecular beacons (paragraph 216, in particular). Schlegel et al further teaches that molecular beacons are useful for quantitating the presence of nucleic acids in a sample (paragraph 216, in particular). Schlegel et al further teaches methods wherein the biological sample is urine (paragraph 12 and 150, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to perform the method taught by the combined teachings of Bussemakers, Clements, and Goessl using any molecular beacon specific for PCA3 mRNA, including one comprising SEQ ID NO:6, and any molecular beacon to detect

PSA mRNA, including one comprising SEQ ID NO:5, because Bussemakers et al teaches the polynucleotide sequences of PCA3 and PSA, rendering any molecular beacon comprising any SEQ ID NO that would detect PCA3 or PSA obvious, and Schlegel et al further teaches that molecular beacons are useful for quantitating the presence of nucleic acids in a sample (paragraph 216, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for using molecular beacons to detect PCA3 and PSA in the method taught by the combined teachings Bussemakers, Clements, and Goessl, including those comprising SEQ ID NO:5 and those comprising SEQ ID NO:6, because Schlegel et al teaches methods of detecting markers of prostate cancer comprising using molecular beacons (paragraph 216, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

In the Reply of 1/30/09, Applicant argues that Schlegel et al does not cure alleged deficiencies of Bussemakers, Clements and Goessl.

The amendments to the claims and the arguments found in the Reply of 1/30/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that Schlegel et al does not cure alleged deficiencies of Bussemakers, Clements and Goessl, the alleged deficiencies of Bussemakers, Clements and Goessl have been addressed above.

Summary

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642